

and effective treatment for a number of diseases and conditions, and because its labeling was false and misleading since the device did not provide audible sound or ultrasound therapy and did not produce audible sound energy or ultrasound energy; and that the device was adulterated when shipped, in that its strength differed from, and its quality fell below, that which it purported to possess since it purported to produce (1) audible sound waves varying from a frequency of 0 to 20,000 cycles per second, and (2) ultrasound waves varying from a frequency of 100,000 to 400,000 cycles per second, whereas the device produced neither sound waves nor ultrasound waves.

The default decree provided for the condemnation of the device and its delivery to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6594. Dr. Bell's Veterinary Medical Wonder. (F.D.C. No. 44912. S. No. 35-675 R.)

QUANTITY: 3,887 individually cartoned bottles at New York, N.Y.

SHIPPED: Between 10-29-59 and 11-27-59, by Juan S. Garcia, Ave. Fdex. Juncos esq. San Andres, Pda. 4, Pta. de Tierra, P.R., San Juan, Puerto Rico, and on 7-11-59, from Kingston, Canada, by Dr. Bell Veterinary Medicine Co.

LABEL IN PART: (Ctn.) "Dr. Bell's Veterinary Medical Wonder * * * Net Contents 15 ml. Dr. Bell Veterinary Medicine Co., Kingston, Ontario, Canada * * * Each ml. contains 0.25 ml. Aconite Fluid Extract; 0.25 ml. Belladonna Root Fluid Extract; 0.25 ml. Digitalis Fluid Extract; 0.1875 ml. Liquid Extract of Nux Vomica."

ACCOMPANYING LABELING: Leaflet in carton entitled "Dr. Bell's VMW Veterinary Medical Wonder."

LIBELED: 10-13-60, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the following statements contained in its labeling: (carton) "A 'first-aid' treatment for animals suffering the effects of injury, shock, exposure, or sudden illness. As an antispasmodic in nervous conditions. A restorative in exhaustion. * * * In acute cases, such as Colic," (leaflet) "A 'First-Aid' for animals displaying symptoms of Shock, Exposure or Sudden Illness. An Antispasmodic in Nervous Conditions A Restorative in Exhaustion. When veterinary service is not available, administer VMW at the first sign of Coughs, Colic, Pain, Fever, Inflammation, etc. * * * Dosages * * * Calf Scours: * * * Shipping Fever: (Hemorrhagic-Septicemia) When 'shipping fever' symptoms are observed: Difficult breathing, dry painful coughs, arched backs, discharges from nose and eyes, high temperature * * * Colic: * * *," and (bottle) "a 'first-aid' for sick animals * * * colic * * * for shock or exposure," were false and misleading since there was no scientific basis for regarding the article as a first aid for sick animals suffering the effects of sudden illness, shock, injury, or exposure; and the article would not act as an antispasmodic in nervous conditions, or as a restorative in exhaustion; 502(a)—the labeling contained statements which represented and suggested that the article was an adequate treatment for the diseases, conditions, and symptoms referred to therein, which statements were false and misleading since the article was not an adequate treatment for such diseases, conditions, or symptoms; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended.

DISPOSITION: 2-21-61. Consent—claimed by E. Vadillo Ruiz, Inc., New York, N.Y., and released under bond for export to the original foreign supplier, Dr. Bell Veterinary Medicine Co., Kingston, Canada.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

6595. Elixir of phenobarbital and belladonna. (F.D.C. No. 45301. S. No. 2-739 R.)

QUANTITY: 4 50-gal. drums at Atlanta, Ga.

SHIPPED: 10-18-60, from Greenville, S.C.

LIBELED: 12-21-60, N. Dist. Ga.

CHARGE: 501(a)—contained plant fibers, metallic particles, and whole insects while held for sale.

DISPOSITION: 2-6-61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE*

6596. Ferrous sulfate tablets. (F.D.C. No. 45505. S. No. 99-459 R.)

QUANTITY: 53 100-tablet btl. at Gardiner, Maine.

SHIPPED: 11-9-60, from Worcester, Mass., by Buffington's, Inc.

LABEL IN PART: (Btl.) "Entells VIRON * * * Ferrous Sulfate Exsiccated 5 grains. Entells designates Buffington brand Enteric Coated Tablets. Dose: * * * Buffington's Inc. * * * Worcester, Mass."

LIBELED: 3-8-61, Dist. Maine.

CHARGE: 501(b)—when shipped, the article purported to be, and was represented as, *ferrous sulfate tablets*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and was represented to be enteric-coated, and its quality fell below the official standard for enteric-coated tablets since the articles failed to meet the disintegration requirements for enteric-coated tablets as provided in the official compendium; and 502(a)—the label statement "Ferrous Sulfate Exsiccated 5 grains" was false and misleading as applied to the article which purported to supply 5 grains of ferrous sulfate in a form assimilable to the body but failed to do so.

DISPOSITION: 3-23-61. Default—destruction.

6597. Cecobee vitamin injectable. (F.D.C. No. 45521. S. No. 14-934 R.)

QUANTITY: 80 ctnd. vials at Cincinnati, Ohio.

SHIPPED: 1-27-61, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories, Inc.

LABEL IN PART: (Bulk ctn.) "20 cc. No. 1109 Multiple Dose Vial B₁₂ Plex C A Stable B Complex with B-12 and C Caution: * * * Phila. Ampoule Laboratories Philadelphia 23, Pa. * * * Each cc. contains: * * * Thiamine HCl 50 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B₁₂.

The article was shipped in bulk cartons of 50 unlabeled vials each and after receipt by the dealer, each vial was labeled and packed in individual cartons.

*See also No. 6593.